4160-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 109

[Docket No. 77N-0080]

POLYCHLORINATED BIPHENYLS (PCBs) IN FISH AND SHELLFISH; REDUCTION OF TOLERANCES; FINAL DECISION

AGENCY: Food and Drug Administration.

ACTION: Final rule; final decision following a formal evidentiary public hearing.

SUMMARY: The Commissioner of Food and Drugs is issuing a Final Decision following a formal evidentiary hearing to consider objections to the agency's final rule concerning a tolerance for polychlorinated biphenyls ("PCBs") in fish and shellfish. The Commissioner concludes that the appropriate tolerance, after taking into account public health and human food loss considerations, is 2 parts per million ("ppm"), as provided for in the final rule.

EFFECTIVE DATE: (Insert date 90 days after date of publication in the Federal Register.)

ADDRESS: The testimony and evidence submitted, the initial decision, and all other documents cited in this decision may be seen in the Dockets Management Branch (HFA-305), Rm. 4-62, 5600 Fishers Lane, Rockville, Md., 20857, from 9 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Allen Heim, Ph.D., Office of Science Coordination, HF-8, Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, Md., 20857, 301-443-1587.

SUPPLEMENTARY INFORMATION:

I. BACKGROUND

This rulemaking proceeding involves the tolerance for unavoidable residues of PCBs in fish and shellfish, 21 C.F.R. § 109.30(a)(7). In 1977 the Food and Drug Administration ("FDA") proposed to lower the tolerance for PCBs in several classes of food. In relevant part, FDA proposed to lower the tolerance in fish and shellfish from 5 ppm to 2 ppm. 42 Fed. Reg. 17487 (April 1, 1977). In 1979 the agency promulgated a final rule based on the proposal, including lowering the tolerance in fish and shellfish to 2 ppm. 44 Fed. Reg. 38330 (June 29, 1979).

Section 406 of the Federal Food, Drug, and Cosmetic Act ("the act"), 21 U.S.C. 346, authorizes the establishment of tolerances for poisonous or deleterious substances added to food that cannot be avoided by good manufacturing practice. PCBs are such a substance. Although the agency's paramount concern is protection of the public health, under section 406 the agency must consider, in establishing a tolerance, the extent to which a contaminant is unavoidable. In

essence, the agency is permitted to find where the proper balance lies between adequately protecting the public health and avoiding excessive losses of food to American consumers. 44 Fed. Reg. 38330-31. Pursuant to that mandate, the agency examined the amount of commercial fish that would be lost as human food as a result of lowering the tolerance.

As required by section 701(e) of the act, 21 U.S.C. 371(e), which applies to regulations promulgated under the authority of section 406, FDA provided persons who would be affected adversely by the final rule an opportunity to object and request a formal evidentiary hearing. Over 20 persons objected to provisions of the final rule concerning fish and shellfish, but only the National Fisheries Institute, Inc. ("NFI") requested a hearing. 44 Fed. Reg. 57389 (October 5, 1979). As provided by section 701(e)(2) of the act, that objection and request for hearing automatically stayed the effective date of the final rule, pending resolution of the issues raised in NFI's objection. In the Federal Register of May 1, 1981, FDA announced a formal evidentiary hearing on NFI's objection, on the issue of the "magnitude of the human food loss" from reducing the tolerance to 2 ppm. 46 Fed. Reg. 24551. NFI and FDA's Bureau of Foods[1/] ("Bureau")

1/ The Bureau of Foods is now named the Center for Food Safety and Applied Nutrition.

were parties at the hearing. In addition to the parties, the National Marine Fisheries Service ("NMFS") of the U.S. Department of Commerce and the Environmental Defense Fund ("EDF") filed notices of participation. EDF subsequently withdrew from participation.

Administrative Law Judge ("ALJ") Daniel J. Davidson issued his Initial Decision on February 8, 1982. FDA announced the availability of the Initial Decision in the Federal Register of March 9, 1982. 46 Fed. Reg. 10079. NFI and the Bureau filed exceptions to Judge Davidson's Initial Decision under 21 C.F.R. § 12.125.

I am issuing this Final Decision under section 406 of the act and 21 C.F.R. § 12.130. In taking this action, I have all the powers I would have had in making the Initial Decision. 21 C.F.R. § 12.130(a). Section II of my Final Decision discusses Judge Davidson's Initial Decision, evidence and testimony introduced during the hearing, the exceptions filed by the Bureau and NFI, and my resolution of the hearing issue.

Although the hearing was limited to the issue of the magnitude of human food loss, the agency invited interested persons to submit other relevant materials for possible inclusion in the rulemaking record. Participants could argue in briefs to the Commissioner that a different tolerance should be set. 46 Fed. Reg. 24553. NFI, the Bureau, NMFS,

EDF, the Chemical Manufacturers Association ("CMA"), the General Electric Company ("GE"), the State of Michigan, and others submitted additional information, briefs, or both.

Section III of my Final Decision discusses the scientific issues raised in these submissions and briefs. Section IV deals with several miscellaneous issues. In Section V, I balance the magnitude of the human food loss that would result from lowering the tolerance to 2 ppm and the public health risks from PCBs. My ultimate conclusion is that a tolerance of 2 ppm for PCBs in fish and shellfish adequately protects the public health, while not causing excessive loss of food to American consumers.

II. THE EVIDENTIARY HEARING ISSUES

A. The Initial Decision

Judge Davidson made detailed findings about the human food loss resulting from lowering the tolerance from 5 ppm to 2 ppm:

IMPORTS	$	0
UNVIABLE FISHERIES		0
RELATED SPECIES		0
DOMESTIC HARVEST IN VIOLATION		
Alewives	$	843,900
Buffalofish		128,000
Carp		223,000
Catfish		3,884,000
Trout		80,000
Whitefish and Chubs		1,161,000
Bluefish		68,000
Lobster		4,081,600
Striped Bass		2,984,000
TOTAL	$	13,453,500
Times Multiplier of Six	$	80,721,000
Elasticity Effect		6,000,000
GRAND TOTAL	$	86,721,000

Initial Decision, Appendix 2 (footnotes omitted).

Judge Davidson's figures are in 1980 dollars.2/ The loss figures for the individual species are dockside values; except for alewives, they are not now in dispute. Judge Davidson determined the human food loss at 2 ppm by subtracting the loss at 5 ppm from the loss at 2 ppm so as to represent the net loss from reducing the tolerance. He concluded that retail value is the appropriate measure of

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2/ Unless stated otherwise, all dollar figures in my Final Decision are in 1980 dollars. Conversion from 1974 dollars to 1980 dollars is based on use of the factors in the Initial Decision at page 3, note 3.

human food loss and applied a "multiplier" of six to derive retail value from dockside value.

B. Exceptions to the Initial Decision

NFI excepts to Judge Davidson's figures for imports and unviable fisheries; the Bureau excepts to the figures for alewives and the elasticity effect. Both parties except to the "multiplier" and the grand total. These exceptions, and my resolution of each, are discussed below.

1. Imports

Judge Davidson concluded that no human food loss from imports could be found. Initial Decision at 5. He reasoned that the record contains only unsupported claims of loss due to imports.

NFI excepts to that finding, and argues that the Judge should have found a human food loss of $31,410,000. NFI Exceptions at 5. NFI's figure was derived by assuming that the same percentage of imported fish as domestic fish would exceed a 2 ppm tolerance. Applying those percentages to the value at time of entry into the United States and amount of

imported whitefish, freshwater trout, and lobster,[3/] NFI derived a loss of about $15.7 million, or $31.2 million after the application of a "conservative" multiplier of 2. NFI Exceptions at 6; N-21 at 12. Of the $15.7 million loss, about $400,000 is due to freshwater trout and $500,000 is due to whitefish. The remainder, almost $15 million, is attributed to lobster. See N-21 at 3, 11.

I conclude that no food loss can be attributed to imports. Although neither Judge Davidson nor NFI considered different imported species separately, I believe that it is useful to do so. First, there was specific testimony concerning imported lobsters. Bureau witness Dr. Talhelm testified that no imported lobsters were reported to be violative. G-8 at 16. Dr. Gates testified for the Bureau that imported lobster samples were found to contain no significant levels of PCBs. G-9 at 3, 9. NFI did not rebut any of that testimony. Consequently, I conclude that no food loss can be attributed to imported lobster.

I agree with Judge Davidson's reasoning as applied to freshwater trout and whitefish. Except for lobster, there

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3/ NFI witness Dr. Strand apparently based his calculations on the assumption that 28.6% of all lobsters would violate a 2 ppm tolerance. See N-21 at 3. However, Judge Davidson found only 10% of lobster would violate a 2 ppm tolerance. Initial Decision at 7. Although NFI did not except to that finding, it continues to use, without explanation, the 28.6% figure in its exception concerning imports.

was no testimony concerning PCB levels in imported fish. NFI's food loss argument is based on the fact that "[t]he PCB sample data were, in many instances, drawn from the marketplace." NFI Exceptions at 6. NFI contends that "[t]here is no evidence that imports contain measurably different PCB levels [than domestic landings]." NFI Exceptions at 6. But that contention is based only on the testimony of Dr. Strand, that the "samples of the FDA survey may, in fact, have included imported products." N-21 at 9 (Emphasis added.) As authority, Dr. Strand cited only G-5, a 1979 Bureau of Foods memorandum, which stated "[t]he [NFI] comment assumes that imported species are contaminated to the same extent as corresponding domestic species. It is quite possible they are not, however, ..." G-5 at 1-2. I acknowledge that FDA samples may have included imports. On the basis of the evidence, however, I conclude that any finding concerning a specific human food loss due to imported fish would be speculative. It would not be based on substantial evidence, as required by section 701(e)(3) of the act.

2. Unviable Fisheries

It is not disputed that, as the percentage of fish that exceed the tolerance level may increase due to the tolerance reduction to 2 ppm, some persons engaged in fishing may cease to operate. Some segments of the fishing industry could possibly cease operations completely. 44 Fed.

Reg. at 38335, col. 1. What is in dispute is whether a loss due to "unviable" fisheries can be quantified.

NFI asserted during the hearing that there would be a $51.6 million loss due to unviable fisheries. Judge Davidson declined to include a figure for unviable fisheries in his calculation of the total loss, on the basis that NFI did not adequately substantiate its loss figure. Initial Decision at 6. NFI excepts to that conclusion. NFI states that the total loss due to unviable fisheries should be $361.2 million ($51.6 million times a multiplier of 7). NFI Exceptions at 5.

I conclude that Judge Davidson was correct. NFI's expert witness Dr. Strand derived the $51.6 million figure by assuming that a fishery would become unviable if the percentage of the catch exceeding a 2 ppm tolerance goes above 25%. N-21 at 8-9. Dr. Strand based his calculation on the following statement in a "position paper" by the executive director of the Midwest Federated Fisheries Council:4/

> It should be pointed out that the commercial fisheries of the Great Lakes are already operating at less than 50 percent of the potential annual harvest

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4/ Although NFI contends that Dr. Strand relied only "in part" on this statement, NFI Exceptions at 3, Dr. Strand's testimony does not indicate any other source for his assumptions. See N-21 at 8.

> ... A 25% reduction in the present level of production (implied by the change from 5 ppm to 2 ppm) would put the fishermen, who are barely making it, out of business completely.

N-21 at 8, quoting from N-18 at 4. (Emphasis added.)

The position paper (N-18) does not state the basis for its contention or how the 25% figure was derived. There is nothing in the record concerning the qualifications of the position paper's author, so there is no basis on which I can conclude that he is a qualified expert on the subject. Moreover, Bureau expert Dr. Talhelm testified that Dr. Strand's use of 25% was arbitrary, and that 10% or 30% could have been used just as well. G-8 at 10. Consequently, I conclude that NFI has not substantiated its claimed loss due to unviable fisheries.

Even if I were to conclude that the evidence supported the use of a 25% trigger level for unviable fisheries, I would derive a much smaller loss attributed to unviable fisheries.5/ I base this result on two factors. First, the statement quoted above addressed only the Great

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5/ Dr. Strand did not indicate how he arrived at the $51.6 million figure, other than to state that it is based on catfish, freshwater trout, striped bass, and lobster. N-21 at 9. Apparently his calculation was based on the total landed value of these species, N-21 at 4, Table 2, reduced by the percent loss for each of those species at 2 ppm, N-21 at 6, Table 3. The reduction is necessary to avoid any double counting, as the value of the violative fish has already been taken into account.

Lakes fisheries. There is nothing in the record concerning a trigger level for other fisheries. Because Dr. Strand's calculations included two marine species, striped bass and lobster, which are not found in the Great Lakes, see N-2, no loss attributed to these marine species could be included.

Second, NFI states in its exceptions that:

> in applying the unviable fishery "trigger," the entire loss to be expected, not the increment between 5 ppm and 2 ppm, must be considered. Judge Davidson's method brings the loss for catfish below the "trigger," whereas it is actually above. Compare Doc. N-21, p.3 with [Initial Decision at] 10.

NFI Exceptions at 5, n. 4. Specifically, the data for catfish indicate a 26.0% loss at a tolerance of 2 ppm, and a 4.7% loss at 5 ppm. N-21 at 3, Table 1. Judge Davidson based his calculations on the incremental loss in reducing the tolerance from 5 ppm to 2 ppm (i.e., for catfish, on a net loss of 21.3%, obtained by subtracting 4.7% from 26.0%. Initial Decision at Appendix 1). No one excepted to that method of calculation. The statement by the executive director of the Midwest Federated Fisheries Council quoted above, on which NFI relies, clearly discusses a "reduction in the present level of production (implied by the change from 5 ppm to 2 ppm)." (Emphasis added.) Applying that statement, the reduction in the level of catfish production is 21.3%.

Because the amount lost is below the 25% trigger level, no loss can be attributed to an unviable catfish fishery.

Consequently, after elimination of the two marine species and catfish, a loss for unviable fisheries can be calculated only with respect to trout. Even if I were to include any loss due to unviable fisheries, it would only be $179,000.6/

3. Alewives

Judge Davidson found that reducing the tolerance from 5 ppm to 2 ppm would result in the annual loss of alewives with a dockside value of $843,900. He arrived at this figure based on testimony that 70% of all alewives caught nationally were taken from the Great Lakes, and that Great Lakes alewives are not used as human food. Therefore, he assumed that the human food loss would, at a maximum, be 30% of the domestic catch (30% of the annual catch of $2,813,000 (N-21

6/ The incremental loss of trout from reducing the tolerance from 5 ppm to 2 ppm is 30.7% (Initial Decision, Appendix 1), which exceeds the 25% trigger level. The $179,000 figure is based on annual landings of trout worth $259,000 (Table 2, N-21 at 4), reduced by $80,000, the value of violative trout at a 2 ppm tolerance that have already been taken into account (Initial Decision, Appendix 2).

at 4, Table 2) equals $843,900).[7] Initial Decision at 7.

The Bureau excepts to that figure, and asserts that no loss should be attributed to alewives. The Bureau's argument is that the record does not support Judge Davidson's assumption that 30% of the alewife harvest is used for food. Bureau Exceptions at 4.

I do not agree with the Bureau. Bureau expert Dr. Talhelm testified that "[a]lewives on the east coast of the United States, I believe, are used for human food consumption." G-8 at 5. I conclude that his statement is sufficient support for the finding that 30% of the alewife catch is used for human food.[8]

4. Multiplier

In the proposal, FDA stated that the processed value of fish is about seven times its landed or dockside value; "processing" includes "cleaning, canning, distributing, retailing, etc." 42 Fed. Reg. 17492, col. 2. The preamble to the final rule discussed only landed value.

7/ Judge Davidson implicitly assumed that all alewives would violate a 2 ppm tolerance. See N-21 at 2, 3. That assumption is not in dispute.

8/ Approximately 70% of the U.S. alewife catch comes from the Great Lakes; the remaining 30% comes from the east coast. G-7 at 14-15; see G-2 at 51.

During the hearing, the Bureau argued that the most appropriate measure of human food loss is the dockside value. Bureau Brief to ALJ at 9-10. In the alternative, the Bureau argued that a "multiplier" of two or three should be used to calculate retail value from dockside value, and in essence disavowed use of the multiplier of seven. Id. at 14. NFI's position was that the agency had developed the multiplier of seven and the Bureau was bound by that figure. NFI Brief to ALJ at 3-4.

Against this background Judge Davidson decided that retail value represents human food loss, and found that the appropriate multiplier is six. Initial Decision at 5. Both the Bureau and NFI except to that finding. The Bureau states that the multiplier should be one or three. Bureau Exceptions at 5. NFI takes the position that the multiplier should be seven. NFI Exceptions at 7.

I conclude that it is appropriate to measure human food loss in dockside value, rather than value after processing or retail value. Although the preamble to the proposal and the economic analyses prepared for the proposed and final rules (G-1 and G-2) all discuss both landed and processed value, the preamble to the final rule does not. Thus, that preamble reveals that the agency's decision to lower the tolerance to 2 ppm was based, in the final analysis, on the assumption that the resulting human food loss would have a landed value

of $9.6 million ($5.7 million in 1974 dollars). I believe it is appropriate that my decision on the hearing issue provide an answer that can be directly compared with that $9.6 million figure. Having reached this conclusion, I need not decide whether Judge Davidson's use of a "multiplier" of six to derive retail value from dockside value was correct.

Moreover, based on economic principles, I believe that landed value is the most appropriate measure for human food loss. In the short-run fishermen must bear the brunt of loss due to reducing the tolerance. In the short run, fishermen use their resources to catch fish without knowing whether the fish will violate the PCB tolerance. If the fish cannot be sold, the fisherman loses what he would have received for the fish but for the tolerance -- the landed or dockside value. Persons in the marketing chain such as processors and retailers, and consumers, are not as fixed in the short run. For example, a processor typically has many suppliers of fish. If the processor cannot buy from one source, it probably can make up the difference from alternate sources. Similarly, consumers can react easily by shifting consumption patterns to other species of fish or other foods. Because of this ability to turn to different sources of supply, a lower tolerance level will not have a direct effect on these sectors of the economy and the value that would have been added by processing, distributing, and retailing to the

landed value of fish that violate the lower tolerance should not be considered.

5. Elasticity Effect

Based on the testimony of Bureau witness Dr. Talhelm, Judge Davidson found that there would be a $6 million annual cost due to the "elasticity effect." He reasoned that lowering the tolerance would increase the value of the fish remaining on the market by no more than that amount. Initial Decision at 7.

The Bureau points out that the Judge misread Dr. Talhelm's testimony. Bureau Exceptions at 3. The Bureau is correct. What Dr. Talhelm actually stated was "I am positive that, even under these additional assumptions [the price elasticity of fish], the estimated landed value of the losses would still be less than $6 million per year." G-8 at 18 (Emphasis added.) Because Dr. Talhelm did not provide any estimate of the loss due to the elasticity effect, I conclude that a specific dollar loss cannot be attributed to the elasticity effect.

NFI attempts to bolster Judge Davidson's finding by arguing that it represents (after taking into account a multiplier effect of six) a dockside loss of $1 million, "which is an entirely reasonable estimate." NFI Reply to Exceptions at 2. I conclude that this argument is without merit, as it is nothing more than an attempted post hoc

rationalization without evidentiary support. Moreover, it is based on a total misreading of the testimony. Since Dr Talhelm testified about "landed" value, the reduction of his estimate by the "multiplier" to derive dockside value is obviously incorrect, as the terms landed and dockside are synonymous.

C. Conclusion

I have concluded that Judge Davidson correctly found that there would be no quantifiable human food loss due to imports or unviable fisheries, and that he correctly calculated the potential loss due to alewives. I have also concluded that human food loss should be stated in term of dockside or landed value, and that no specific loss can be attributed to the elasticity effect. Therefore, I find that the human food loss in 1980 dollars, from reducing the tolerance from 5 ppm to 2 ppm, is $13,453,500 landed value.9/

Although Judge Davidson also calculated the human food loss for tolerances from 2.5 ppm to 4.5 ppm, those calculations are incomplete due to the lack of data concerning lobster and alewife losses at these intermediate tolerances. See Initial Decision, Appendix 2, note **.

9/ This is the same figure calculated by Judge Davidson, before application of the multiplier and addition of loss due to the elasticity effect. See page 6, supra.

Because these 2 species account for over one-third of the dollar loss at 2 ppm, I conclude that any calculation of the human food loss at intermediate tolerances would be based on speculation rather than substantial evidence. Consequently, I am not making any findings about the human food loss at tolerances between 2 ppm and 5 ppm.

I further conclude that Judge Davidson correctly decided all issues not addressed above.

III. SCIENTIFIC ISSUES

In announcing the hearing concerning the magnitude of the human food loss, the agency stated that information not reasonably available during the notice and comment aspect of this rulemaking relating to other aspects of the tolerance, including the toxicity of PCBs, could be submitted for consideration by the Commissioner if the Commissioner finds good cause for their late inclusion in the rulemaking record. 46 Fed. Reg. 24552, col. 2. Hearing participants and other interested persons submitted over 100 scientific articles and reports for consideration by the Commissioner. Some of these articles and reports were discussed in the agency's risk assessment ("Risk Assessment") supporting the final rule (44 Fed. Reg. 38340, reference 45), some were available at that

time but were not discussed, and some were written after the date of the risk assessment.

In view of the changing nature of scientific knowledge and the public health importance of a tolerance for PCBs in fish and shellfish, it is important that the agency's decision be based on all currently known relevant information. Therefore, I conclude that there is good cause for including in the rulemaking record all newly submitted reports and studies that are not presently part of the record. This includes those newly submitted studies that were reasonably available at the time of the notice and comment part of this rulemaking, but that were not then submitted for whatever reason.

I am aware that none of the additional submissions answer many of the uncertainties that FDA acknowledged in the preamble to the proposal (e.g., studies involved commercial grade PCB mixtures, rather than the PCB isomers in fish, see 42 Fed. Reg. 17488), cols. 2 and 3). Nevertheless, the submissions are relevant to the toxicity of PCBs and a final decision on the tolerance, so I reject NMFS's suggestion that the Bureau's submissions not be included in the rulemaking record. NMFS Reply Brief at 5.

The Office of Science Coordination has reviewed all submitted papers. The results of that review are summarized in a report that is available from the Dockets Management

Branch. ("Report"). I agree with the results of that review, and adopt the Report as part of my Final Decision. That review concluded that the newly submitted data support the conclusions of the Risk Assessment upon which the final rule is based.

In their briefs, NFI and GE generally take the position that FDA's concerns about the potential health risks associated with PCBs are overstated. I do not agree with that position. My responses to their specific arguments follow.

NFI argues that FDA's concerns are unfounded because PCBs are only a cancer promoter, not an initiator. NFI Brief at 5. Presently, there is no consensus in the scientific community regarding the mechanisms of initiation and promotion. However, regardless of whether PCBs are promoters or initiators, I believe the data indicate that PCBs present a significant potential risk to our population. In the preamble to the final rule, FDA stated that "[a]lthough the data do not fully resolve such important questions as the carcinogenicity of PCB's, they lead to the conclusion that neither 'no-effect' nor 'allowable daily intake' levels for PCB's can be established with any confidence and that, from a toxicological point of view, human exposure to PCB's should be reduced." 44 Fed. Reg. 38331, col. 2. I conclude that that statement continues to be valid today.

NFI and GE contend that PCB levels in fish pose no health problems. NFI Brief at 5; GE Brief at 9-10. I do not agree. NFI and GE cite a study that investigated potential adverse health effects from human consumption of Lake Michigan fish contaminated with PCB residues. The study was considered in the Risk Assessment and discussed in the preamble to the proposal, 42 Fed. Reg. 17492-93 (Reference 40). Although no adverse health effects or groups of symptoms that were clearly related to PCB exposure could be identified in the exposed group, the investigators reported a highly significant correlation between the quantity of Lake Michigan fish consumed and the concentration of PCBs in the blood of study participants. It is significant that abstinence from Lake Michigan fish consumption for a period of 90 days did not significantly change PCB blood levels. Moreover, the study's authors cautioned that the absence of any adverse health effects similar to those effects observed in workers exposed to PCBs does not exclude the possibility that long term effects will occur.

NFI states that occupational exposure to PCBs at levels very much higher than would be experienced by those ingesting contaminated fish "leads to some health problems but not cancer or chronic health problems." NFI Brief at 5-6. FDA has identified a potential risk of PCB-induced hepatocellular

carcinoma and adenoma by use of data from rodent carcinogenesis bioassays. Report at 4. This risk is supported by data in non-human primates and man indicating that the liver is a target of PCBs. Report at 5-6. There are also reports that an increased incidence of cancer has been observed in workers exposed to PCBs (Brown and Jones (1981)).10/ Although the incidence is low and a cause-and-effect relationship has not been established, these data -- coupled with the fact that cancer has a long latent period -- support the conclusion that chronic exposure to PCBs through the diet poses a potential risk.

GE argues that, because extrapolation of animal data to human experience is difficult and often misleading, priority should be given to valid human data. GE Brief at 3. I agree. The agency would prefer to base its risk assessment completely on valid human data. 42 Fed. Reg. 17487-88. However, there are rarely enough adequate human data to assess actual human risk without using data from non-human studies. There is general consensus among scientists that properly conducted animal studies are useful in the assessment of human health risks. Here, the results of human and animal data show a significant similarity of PCB-related

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10/ Citations are to references in Appendix I of the Report.

effects between animals and human beings. For example, a review of the available carcinogenesis data in 1978 compared the responses of man, monkey, and rat to PCBs and concluded that hepatic hypertrophy was one of the responses common to all species (IARC (1978); see Table 9, p. 70). Liver has been found to be the predominant target organ in rodents and abnormal liver function has been observed in human beings exposed to PCBs in the workplace. Report at 5-6. Also, an abnormal incidence of liver cancer was reported in a population of PCB exposed workers (Brown and Jones (1981)).

I recognize that remaining unanswered questions about the human response to PCBs probably will be resolved only by valid human data. Nevertheless, submitted data not available at the time of the Risk Assessment underscore the agency's concerns about PCBs and support the hypothesis that the human liver is a target of PCBs and may be adversely affected by exposure to PCBs. Under section 406 of the act, FDA must make a qualitative judgment on the basis of available data -- however incomplete -- to insure the proper balance between adequate public health protection and excessive loss of food. Therefore, I conclude that the extrapolation of the animal data is both necessary and proper.

GE suggests that, because PCB-induced morphological changes in the gastric mucosa of monkeys are not reported in rodents or other species, and because there are no clinical

findings suggesting increased occurrences of stomach cancer in man, extrapolation from animal models to man is not appropriate. GE Brief at 4. I believe GE's suggestion misses the point, as the human liver, not the stomach, is the principal source of concern.

GE contends that animal studies do not clearly indicate that PCBs induce cancer. GE Brief at 6. Although the question of whether PCBs are carcinogenic still has not been fully resolved, results of studies completed since the Risk Assessment support its conclusion that the liver is a target organ for PCBs in the rodent and that hepatocellular carcinoma or adenoma can result from PCB ingestion. Eleven of twelve rodent studies submitted in this proceeding reported significant PCB-associated incidences of hepatoma, hepatocellular carcinoma or adenoma, or hepatic neoplastic nodules. Report at 4. These endpoint histopathologies are generally recognized as indicative of carcinogenic or precarcinogenic responses. In addition, Shimada and Sato (1980) reported the finding of a PCB-moiety that was apparently covalently bound to rat hepatic macromolecules. This finding corroborates the animal studies, since it is generally accepted that the finding of intracellular, covalently bound agents is an important step in the mechanism of carcinogenesis. Two general statements can be made. First, there is agreement among scientists that induction of

hepatocellular carcinomas early in the course of a bioassay is indicative of carcinogenicity under bioassay conditions. Nagasaki et al. (1972) observed hepatocellular carcinoma at 32 weeks in mice that were fed PCBs. Second, the occurrence of hepatocellular tumors in more than one species and/or more than one sex gives added weight to a finding of carcinogenicity. Here, increases in hepatocellular tumors were observed in both mice and rats fed PCBs.

Although GE correctly points out that the results of clinical studies with exposed workers have not proved conclusively that PCBs cause adverse liver abnormalities in human beings, GE Brief at 6-7, that point is hardly controlling. What is important is that the results of the studies do raise concerns about the response of the human liver to PCBs and indicate that the human liver is a target of PCBs. FDA is concerned about the induction of PCB-associated liver abnormalities in human beings as a result of long term, low level exposure to PCBs.

GE contends that PCBs pose no serious risk of teratogenesis to human beings because animal studies showed negative results or highly questionable positive results. GE Brief at 5-6. The concerns raised in the Risk Assessment

about the potential of PCBs to cause reproductive and fetotoxic effects were based on the results of a study in Rhesus monkeys (Barsotti et al. (1976)). Those concerns continue because a subsequent report of behavioral tests with the infant Rhesus monkeys who survived that study indicated increased errors in five of nine learning tasks at ages eight and 24 months, even though they were no longer nursing. During that period, tissue concentrations of PCBs in those infant monkeys decreased linearly with time (Bowman et al. (1978)). This suggests that PCBs may cause irreversible neurobehavioral abnormalities. Additional support for this concern is provided by the results of a study in minks in which PCBs at 2 ppm in the diet caused complete reproductive failure (Bleavins et al. (1980)).

GE contends that "no serious effects on reproduction or infant mortality were found among 100 nursing mothers in Michigan." GE Brief at 5. GE's contention is based on a study that was conducted to measure the levels of PCBs in human milk collected in the state of Michigan (Wickizer et al. (1981)). That study does not support GE's contention, because it did not purport to collect data concerning adverse health consequences to any of the donors. The study is important, however, because it demonstrates that PCBs have been found in human milk at levels (1.5 $\pm$ 0.8 ppm) almost the

same as those levels found in the milk of Rhesus monkeys whose infants displayed significant signs of toxicity.

GE discusses the observation that "in the process of metabolizing PCBs, excess amounts of proteins (enzymes) known as mixed function oxydases (sic) (MFOs) are produced in occupationally exposed individuals, principally in the liver." GE Brief at 10. Contrary to GE's assertion, I do not believe that these data, together with the results of other toxicological experiments, support the conclusion that the observed incease in enzyme activity is of no consequence to health over the individual's lifetime. The fact that an increase in enzyme activity in the human liver was observed supports the conclusion that the liver is a target organ of PCBs in human beings and more generally underscores FDA's concerns about the safety of PCB's to human health.

GE discusses "Yusho disease." GE Brief at 7. The Yusho tragedy helped alert the public and this agency to the dangers of PCB contamination. It is discussed in the preamble to the proposal, 42 Fed. Reg. 17488, col. 1, and in the Risk Assessment. However, the Yusho incident involved short-term exposure to high levels of PCBs, while the focus of this proceeding is the long-term ingestion of low levels of PCBs. Gaffy (1981), in a paper submitted by CMA, stated that "it is doubtful whether any generalization can be made from the [Yusho] incident to lower level environmental or

occupational exposures to PCBs." Therefore, I will not respond to GE's specific contentions concerning Yusho disease. Similarly, dermatological ailments, see GE Brief at 9, are not the focus of FDA's concerns.

I have considered the scientific arguments of EDF and the Bureau in making my final decision. Because their arguments support the final rule, I will not address them specifically.

IV. MISCELLANEOUS ISSUES

Several miscellaneous issues were raised in the briefs to the Commissioner and other pleadings. They are addressed in this section of my decision.

NFI argues that the agency unlawfully interpreted NFI's objection to the final rule in an overly narrow way, thereby denying it the right to a hearing on some issues. NFI Brief at 8-11. But that contention is not borne out by an examination of NFI's objection. NFI objected "on the grounds that the loss of food which would be caused by the proposed reduction of the tolerance is grossly understated by the agency ..." N-1 at 1. That is precisely the issue on which FDA granted a hearing -- "the magnitude of the human food loss (in terms of dollars, poundage, percentage of catch,

etc.) that would result from lowering the tolerance of PCB's in fish from 5 ppm to 2 ppm." 46 Fed. Reg. 24552, col. 2.

NMFS argues in its brief to the Commissioner that FDA should perform a new risk analysis that specifically takes lobster into account. NMFS Brief at 6. At the time of the Risk Assessment, no data concerning PCB levels in lobster were available.

In response to that argument, a Bureau scientist recalculated the risk estimates, taking residue PCB levels in lobster into account. Those calculations show that the overall risk estimates would increase by 1.5% at most. The Bureau scientist's report is attached to the Bureau's reply brief to the Commissioner. Because the Bureau's calculations establish that the Risk Assessment results are still valid, no purpose would be served by further delaying the effective date of the 2 ppm tolerance while a new risk assessment is performed.

NFI filed a motion to strike that recalculation of the Risk Assessment, on the basis that the evidentiary record had closed and that NFI would be prejudiced because it would not have a chance to rebut the Bureau's recalculations. I am denying NFI's motion to strike and conclude that it is without merit. In its response to the motion to strike, the Bureau stated that it would not oppose the submission of any rebuttal information by NFI. Because NFI did not even

attempt to rebut the Bureau's recalculation, it is obvious that NFI has not been prejudiced. Moreover, the recalculation was submitted for consideration by the Commissioner. It had nothing to do with the hearing issue and was not affected by the closing of the hearing evidentiary record.

NMFS also argues in its reply brief that FDA should undertake a new risk assessment that takes into account tolerance levels between 2 ppm and 5 ppm. NMFS stated that it would work with FDA in supporting such an endeavor. NMFS Reply Brief at 14.

As the agency previously stated, it must act on the basis of existing information, even if incomplete. 44 Fed. Reg. 38331, col. 1. FDA would not be fulfilling its obligation to protect the public health by further delaying the effective date of the reduced tolerance. I acknowledge NMFS's offer of assistance, and will consider it in connection with FDA's on-going monitoring of PCBs and, if necessary, future revisions of the tolerance.

NFI argues that FDA failed to comply with the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., and Executive Order 12291, 46 Fed. Reg. 13192 (February 19, 1981). NFI Brief at 12. That argument is answered by the plain language of that Act and Order. Section (1)(a)(1) of the Executive Order states that it does

not apply to administrative actions governed by 5 U.S.C. 556 and 557, which apply to rulemakings pursuant to section 701(e) of the act. The Regulatory Flexibility Act does not apply to rulemaking initiated before its effective date, January 1, 1981. P.L. 96-354, § 4.

NFI contends that FDA should conduct a much broader inquiry into the economic costs of the reduced tolerance on the nation. NFI Brief at 11. On the other hand, EDF argues that economic considerations cannot play a significant part in this rulemaking. EDF Brief at 4-10. As discussed in the preamble to the final rule, 44 Fed. Reg. 38330, col. 3, the agency's paramount consideration in establishing a tolerance is protection of the public health. FDA is authorized by section 406 of the act to consider the unavoidability of substances such as PCBs. It is in connection with the unavoidability of PCBs that human food loss, and thus the limited issue of the value of the food loss, are relevant.

V. CONCLUSION

In promulgating the final rule, the agency concluded that a 2 ppm tolerance would strike a proper balance between protecting consumers from the risks associated with exposure to PCBs, and the loss of food due to the lowered tolerance. That balancing was based on an estimated annual

food loss, in terms of landed value, of $9.6 million ($5.7 million in 1974 dollars). For the reasons discussed in the preamble and supporting economic analysis (G-2), that estimate was based on a number of assumptions and inherently subject to considerable uncertainty.

I have concluded above that the annual dockside human food loss is $13.5 million, rather than the $9.6 million estimate stated in the preamble to the final rule. I have further concluded that the Risk Assessment supporting the final rule continues to be valid in light of newly submitted scientific information. The only question that remains is whether a balancing of the unchanged public health considerations and the increased human food loss yields a tolerance greater than 2 ppm. I conclude that the answer is no. I conclude that, even with an estimated human food loss of $13.5 million rather than $9.6 million, 2 ppm is nevertheless the proper balance between public health protection and loss of food.

I believe that we should keep in mind the fact that total annual domestic landings of fish are almost $1.6

billion.11/ Thus, the total human food loss is less than 1% of all domestic landings.

NMF argues that, based on a balancing of risks to human health and human food loss considerations, the tolerance should be 3.5 ppm. NMFS Brief at 4. Although the risk assessment supporting the final rule included calculations of risk only at 5 ppm, 2 ppm, and 1 ppm, NMFS submitted the results of risk calculations at various levels between 5 ppm and 2 ppm.12/ F-32 and F-33.

I do not agree with NMFS's reasoning. The risk calculations for tolerances between 5 ppm and 2 ppm do not show any sudden decrease in the number of expected cancers below the 3.5 ppm level. Rather, the expected cancer rate drops quickly between 2 ppm and 1 ppm. Those calculations show that the expected cancer rate is basically an arithmetic progression at levels between 5 ppm and 2 ppm and are consistent with my final decision that 2 ppm is the

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11/ According to the economic analysis for the final rule, domestic landings in 1974 were $932 million. G-2 at 3. Expressed in 1980 dollars, that figure becomes $1.56 billion.

12/ Judge Davidson granted the motions of the Bureau and EDF to strike these submissions because they were beyond the scope of the hearing. Order, dated October 16, 1981. Judge Davidson's decision on the motions was correct. For the reasons already stated, however, page 20 supra, the submissions are part of the overall rulemaking record and can be considered by the Commissioner in making a final agency decision.

appropriate tolerance. Moreover, NMFS's argument is based on a comparison of Judge Davidson's total human food loss findings at 2 ppm and 3.5 ppm. As I have already stated, Judge Davidson's human food loss figures for intermediate tolerances are seriously incomplete, such that no meaningful comparisons between 2 ppm and higher tolerances are possible.

NFI and GE argue that a balancing of economic costs and public health benefits leads to the result that the tolerance should be 5 ppm. NFI Brief at 14; GE Brief at 11. I have already discussed and rejected the arguments that the agency's public health concerns about PCBs are overstated, and that FDA has not considered the full economic impact of reducing the tolerance. Consequently, I reject the suggestion that the tolerance not be lowered.

In rejecting the balancing results urged by NMFS, NFI, and GE, I believe it is important to keep in mind that a decision to set the tolerance at 2 ppm, rather than at some other higher or lower level, is inherently judgmental in character. As stated in the preamble to the final rule, section 406 of the act does not provide a formula for weighing public health concerns against loss of food. 44 Fed. Reg. 38336, col. 1. In the final analysis, as Commissioner of the agency charged by Congress with protecting the public health in this area, I must make an

informed judgment in light of the statutory criteria. My judgment is that 2 ppm is the appropriate tolerance.

The foregoing decision in its entirety constitutes my findings of fact and conclusions of law.

List of Subjects in 21 CFR Part 109

Contaminants, Polychlorinated Biphenyls (PCB's).

VI. Final Order

Therefore, on the basis of the foregoing findings of fact and conclusions of law and the record in the above proceeding and under the Federal Food, Drug, and Cosmetic Act (secs. 306, 402(a), 406, 701(a) and (e), 52 Stat. 1045-1046 as amended, 1055, 70 Stat. 919 as amended (21 U.S.C. 336, 342(a), 346, 371(a) and (e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10): It is ordered that the stay of 21 CFR 109.30(a)(7), as ordered in the FEDERAL REGISTER of October 5, 1979 (44 FR 57389), be terminated effective (insert date 90 days after date of publication in the FEDERAL REGISTER).

Dated: MAY 14 1984.

Mark Novitch

Acting Commissioner of Food and Drugs

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